K031074

JON BARRON INC. dba

datrix

OCT 15 2003

510(K) PREMARKET NOTIFCATION SUMMARY

Company: Datrix
Address: 340 State Place
Escondido, CA 92029
Phone: (760) 480-8874
Fax: (760) 480-9474
Contact Person: Lauren Luhmann

Date Prepared: April 2, 2003

Trade Name: VX3 Series Digital Holter Recorder
Common Name: Ambulatory ECG Recorder
Classification Name: Electrocardiograph, Ambulatory (Without Analysis)
(CFR 870:2800)

Description

The VX3 is a lightweight, compact, digital Holter recorder designed for the recording of ECG data collected from ambulatory patients. A derivative of the Datrix DR512 digital Holter recorder, the VX3 has enhanced features, including an LCD to verify leadwire hookup and display recorder status and error messages, optional keypad for selection of various options, and optional pacemaker pulse detection. Various channel and lead configurations are accommodated by using the appropriate leadwire set without additional recorder reconfiguration. Data are recorded on industry standard compact flashcards for subsequent download and to a Holter playback system. Sampling rates are factory programmable to accommodate compatibility with various OEM Holter playback systems.

Intended Use

The VX3 digital Holter recorder is intended for the recording of ECG data collected from ambulatory patients. The recorder can collect data in the presence of implanted pacemaker pulses, and can detect and record the occurrence of signals characteristic of pacemaker pulses. The recorder is used under the order of a physician, who reviews the data after downloading and processing by a Holter playback system. The physician determines the presence of normal and abnormal ECG data as well as pacemaker pulses during the events of the patient's daily activity.

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Predicate Device Comparison

The VX3 is substantially equivalent to other commercially distributed ECG Holter recorders. The following chart compares the VX3 with its predecessor device (Datrix DR512 digital Holter recorder (510(k): K982975), and another predicate device, (Braemar DXP1000 digital Holter recorder (510(k): K993618) with pacemaker pulse detection).

Specification	Datrix VX3	Datrix DR512	Braemar DXP1000*
Functional			
ECG Channels	2 or 3	2 or 3	2 or 3
Resolution	8 or 10 bit (programmable)	8 bit	12-bit sampling/ 10-bit recording
Sample Rate	128 to 512 per channel/sec, programmable	128 to 512 per channel/sec, programmable	256 samples per second
Recording Duration	24 or 48 hours, programmable	24 hours	24 or 48 hours
Memory Type	Non-volatile flash	Non-volatile flash	Non-volatile flash
Data Transfer	Removable flashcard	Removable flashcard	USB interface
Liquid Crystal Display	Yes	No	Yes
Keypad	Yes, optional	No	Yes
Pacemaker Pulse Detection	Yes, optional	No	Yes
Physical			
Dimensions	4.46 x 2.75 x 1.02 in. (113 x 70 x 26) mm	4.94 x 2.75 x 0.94 in.	2.75 x 4.37 x .80 in. (69.9 x 111 x 20.3) mm
Weight	4oz. w/out batteries	4oz. w/out batteries	5oz.(141 gm) w/batteries
Enclosure Material	plastic	plastic	plastic/water resistant
Enclosure flammability	ABS 94-V0	ABS 94-IIB	not available
Operating Position	Any	Any	Any

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Specification	Datrix VX3	Datrix DR512	Braemar DXP1000*
Environmental			
Operating Temperature	0 to 45°C, (32-113°F)	0 to 60°C	0 to 45°C, (32 to 113°F)
Non-operating Temperature	-20 to 65°C (-4 -149°F)		-20 to 65°C (-4 to 149°F)
Operating Humidity	10% to 95%(non-condensing)	8% to 95%	10% to 95%(non-condensing)
Non-operating Humidity	5% to 95% (non-condensing)		5% to 95% (non-condensing)
Operating Altitude/Pressure	700 – 1060 millibars	8000 ft.	not available
Operating Shock	1 meter drop	26 inch drop in pouch	not available
Electrical			
Bandwidth	0.05Hz to 60Hz @-3dB	0.05Hz to 50Hz	0.05Hz to 60Hz @-3dB
Signal Input Range	±2.5 mV 8 bit ±5.0 mV 10 Bit	5mV	not available
Input Impedence	> 5MΩ	>5MΩ	not available
Common Mode Rejection Ratio (CMMR)	> 60dB	60 dB	not available
Power Requirements			
Battery	2 AA or one 9 Volt	One 9 Volt	2 AA or 2 NiMH
Average Operating Current (varies with flashcard)	5 mA @ 9V 5-40 mA @ 3V	5 mA	not available
Peak Operating Current (varies with flashcard)	55 mA @ 9V 250 mA @ 3V	55 mA	not available

** Specifications taken from manufacturer's specification sheet*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Datrix
c/o Ms. Lauren M. Luhmann
Quality Assurance Manager
340 State Place
Escondido, CA 92029

Re: K031074
Trade Name: Digital Ambulatory ECG Holter Recorder Model VX3 and VX3i
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: July 18, 2003
Received: July 21, 2003

Dear Ms. Luhmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

The VX3 digital Holter recorder is intended for the recording of ECG data collected from ambulatory patients. The recorder can collect data in the presence of implanted pacemaker pulses, and can detect and record the occurrence of signals characteristic of pacemaker pulses. The recorder is used under the order of a physician, who reviews the data after downloading and processing by a Holter playback system. The physician determines the presence of normal and abnormal ECG data as well as pacemaker pulses during the events of the patient's daily activity.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031074